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Re-evaluation Note REV2018-14

Re-evaluation Project Plan for Difenoconazole

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Background

In Canada, difenoconazole is under re-evaluation by Health Canada's Pest Management Regulatory Agency (PMRA). The PMRA re-evaluates registered pesticides to determine whether the use of these products continues to be acceptable in terms of value, human health and the environment according to current standards.

Difenoconazole is a fungicide registered for use as a seed treatment or a foliar spray on a wide range of crops. As of 24 July 2018, a total of 28 products containing difenoconazole are registered in Canada, including one technical grade active ingredient, one manufacturing concentrate, and 26 commercial-class end-use products.

Under the authority of section 16 of the *Pest Control Products Act*, the registrant of difenoconazole was notified of the initiation of the re-evaluation of difenoconazole. Following this, the registrant of difenoconazole technical grade active ingredient in Canada indicated support of all uses included on the labels of end-use products in Canada.

The re-evaluation project plan below outlines the timeline, the anticipated areas of focus for the risk assessments, and the data requirements for the re-evaluation of difenoconazole.

Re-evaluation Project Plan

Anticipated Re-evaluation Timeline

The re-evaluation of difenoconazole is defined as a Category 2 as described in Regulatory Directive DIR2016-04, *Management of Pesticides Re-evaluation Policy*. However, because this re-evaluation was initiated prior to the publication of DIR2016-04, the proposed re-evaluation decision for difenoconazole is anticipated to be published for consultation by June 2019. The re-evaluation timeline may be updated if, during the risk assessment, the PMRA identifies additional areas of focus that should be considered.

Human Health Risk Assessment

New assessments will be conducted for toxicology, dietary exposure and occupational exposure (seed treatment uses). Existing assessments with minor updates are considered to be adequate to support the re-evaluation of difenoconazole for the other aspects of human health assessment (such as non-seed treatment uses).

Environmental Risk Assessment

New assessments will be conducted for environmental fate and environmental exposure (seed treatment uses). Existing assessments with minor updates are considered to be adequate to support the re-evaluation of difenoconazole for the other aspects of environmental assessment (such as non-seed treatment uses).

Value

The value of difenoconazole will be considered. The viability of alternatives will be examined for certain uses if risks of concern requiring mitigation are identified.

Data Requirements

The PMRA has identified the need for the technical registrant to provide data for difenoconazole related to toxicology and the environment. Available data have been submitted to the PMRA. A summary of the data call-in is found in the PMRA's Public Registry. For a list of data categories that have been required, see Appendix I. In addition, information regarding the registered use pattern has been requested and received from the registrant, to inform the risk assessments.

Additional Information

The PMRA documents can be found in the Pesticides section of Canada.ca. The PMRA documents are also available through the Pest Management Information Service:

Phone:	1-800-267-6315	within Canada, or
	1-613-736-3799	outside Canada (long distance charges apply)
Fax:	1-613-736-3798	
E-mail:	hc.pmra.info-arla.sc@canada.ca	

Appendix I Data Required Under Subsection 19(1) of the *Pest Control Products Act* for the Re-evaluation of Difenoconazole

Toxicology Data

DACO	Title
4.3	**Short-term Studies – Technical Grade Active Ingredient**
4.3.3	Short-term Oral (28-day)
4.5	**Special Studies – Technical Grade Active Ingredient**
4.5.5	Genotoxicity: In vitro Mammalian Cell Assay
4.5.6	Genotoxicity: In vitro Mammalian Clastogenicity
4.5.8	Other Genotoxicity Studies
4.8	Other Studies/Data/Reports
12.7	Comprehensive Data Summaries

Environmental Chemistry and Fate Data

DACO	Title
8.2	**Laboratory Studies**
8.2.2	**Analytical Methodology (parent compound and transformation products)**
8.2.2.3	Water
8.6	Other Studies/Data/Reports

Environmental Toxicology Data

DACO	Title
9.2	**Non-Target Terrestrial Invertebrates**
9.2.4	**Bees/Insect Pollinators**
9.2.4.1	Bee Adult Acute Contact Toxicity
9.2.4.3	Bee Larvae Toxicity
9.2.4.4	Bee Adult Chronic Toxicity
9.3	**Non-Target Freshwater Invertebrates**
9.3.4	Laboratory Studies with Other Species
9.3.6	Field Studies
9.5	**Fish**
9.5.2	**Acute Studies**
9.5.2.1	Cold Water Fish (rainbow trout)
9.5.3	**Sublethal and Chronic Studies**
9.5.3.1	Fish, Early Life Cycle Toxicity Test
9.5.3.2	Fish, Life Cycle Toxicity Test
9.6	**Wild Birds**
9.6.2	**Acute Studies**
9.6.2.1	Oral (LD_{50}) Bobwhite Quail
9.8	**Non-Target Plants**

DACO	Title
9.8.2	Fresh Water Algae
9.9	Other Studies/Data/Reports
12.7	Comprehensive Data Summaries